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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,634	08/19/2003	Ernest G. Schutt	40,283	7527

7590 03/12/2004

Alliance Pharmaceutical Corp.
6175 Lusk Blvd.
San Diego, CA 92121

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/644,634	Applicant(s) SCHUTT ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 16, the recitation of "The method of claim 14" is confusing as base claim 14 is drawn to "A composition..." Changing claim 16 to "The method..." would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-10, 12-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Feinstein (US 4,774,958).

Feinstein discloses a method of forming stabilized microbubbles for *in vivo* use (ultrasound imaging) comprising providing a first and second gas and a liquid (i.e., water, as an aqueous solution) wherein the first gas and second gas are in a molar ratio as claimed and surrounding the first and second gas with a membrane forming material (i.e., albumin), see abstract, column 3, lines 1-25 and claims. Basically, Feinstein teaches microbubbles and a method for preparing thereof comprising air filled albumin microbubbles, see column 7. The air inherently contains a first gas and second gas as claimed,

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as air is a mixture of gases, mainly, nitrogen at approximately 78% and oxygen at approximately 21%.

Given these percentages and the corresponding atomic weight of such gases, it is readily seen that these two gases are in the molar ratio of the first and second gas as claimed.

Claims 1-5, 7-10, 12-15, 17 and 18 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Widder (US 5,315,997).

Widder discloses a method of forming stabilized microbubbles for *in vivo* use (i.e., imaging), such as ALBUNEX, which is a tradename for air filled albumin microbubbles, see column 5. The albumin microbubbles comprise (i.e., water, as an aqueous solution) and a first gas and second gas that are in a molar ratio as claimed, given that air contains a first and second gas in that is within the molar ratio claimed, see discussion above.

Note: the recitations of a modifier gas and gas osmotic agent do not differentiate over the gases in air, as given their broadest reasonable interpretation, the gases of the prior art encompass these terms. For example, oxygen would modify the properties of nitrogen gas and either gas would have osmotic properties.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,258,339.

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Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,372,195.

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,639,443.

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,280,704

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,626,833.

Claims 1-20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,605,673

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,287,539.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patents listed above are directly within the scope of the pending claims. For example, the patented claims are drawn to microbubble compositions, methods of imaging (see pending claim 13) and/or methods of making contrast agents which include the same components in the generic claim, or in other words, species' encompassed by the patented claims fall entirely within the scope of claims 1 and 14 now claimed. In other words, claims 1 and 14 are anticipated by the claims of the patents. For example, claim 1 of US Pat. 6,372,195, is drawn to a contrast agent composition which is within the genus of claim 14, as it contains microbubbles of gas A and B (wherein the gases have the same properties) and a ratio of gas which encompasses the instant ratio. The pending method of making claims are also obvious in light of the patented composition claims as the only method step is surrounding the gas, which is a required step of the compositions in the patents which are drawn to microbubbles as defined by the patents (i.e., microbubbles cannot be formed without such a surrounding step). While it is noted that claim 1 of the '443 patent recites "a liquid at 37°C at 760 mm Hg," this does not differentiate over the pending claims, which state gas, as the same gases are encompassed, for example, the first gas

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as presently claimed can correspond to the second gas in the patent and the second gas as claimed can correspond to the first gas in the patent, as shown by the dependent claims. Thus, the gas mixtures can be the same and the gases mixtures of claim 1 of '443 are directly within the scope of the pending claims, namely claim 14. The same is true for the claims of Pat. 5,639,443, which defines the gases and the ratio using different terminology, but which includes the same gas mixtures and ratios encompassed by the genus of claim 14 and method claim 1, which again only recites a method step which is an inherent or required step to obtain microbubbles. The claims of Pat. 6,258,339, are drawn to various species' of gas mixtures, and these gas mixtures are within the genus of claim 1 as defined by the specification for gases A and B, and the ratio is within the scope of the gas mixture as claimed. The claims of patents 6,280,704; 6,287,539; 5,605,673 and 5,626,833 are also within the scope of the pending claims or in the alternative, it would have been obvious to one of ordinary skill in the art to modify the present claims to include the additional limitations set forth in the patented claims. The claims of these patents are obvious over some or all of the pending claims as the claimed compositions and methods of making encompass the pending claims or are obvious variations thereof. For example, the claims of '704 include an imaging apparatus; however, as shown by claim 13, the methods of making the compositions are used for imaging, thus, one of ordinary skill in the art would have been motivated to include the methods or composition with such an apparatus so that the imaging could be performed to provide a means for using the prepared microbubbles for their intended use. Also, patents directed to methods of imaging are within the scope of claim 13 now pending which recites that the compositions are made for performing imaging and the only method step provided in the preparation is surrounding the gas which is a requirement for any microbubble, such as those used in the patented claims.

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/029,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are anticipated by the claims of 10/029,712 as the claims of the '712 application are

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drawn to the same basic invention and differ only in a more narrow range of molar ratio of the first gas and second gas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

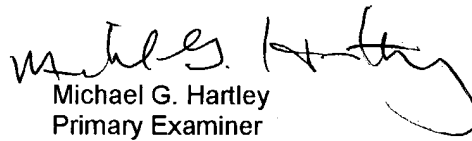
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
Art Unit 1616

3/2/2004